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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/566,826

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Akio Kimura

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1933 7590 08/06/2009  
FRISHAUF, HOLTZ, GOODMAN & CHICK, PC  
220 Fifth Avenue  
16TH Floor  
NEW YORK, NY 10001-7708

EXAMINER

VU, JAKE MINH

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

08/06/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/566,826 | <b>Applicant(s)</b><br>KIMURA ET AL. |  |
|                              | <b>Examiner</b><br>Jake M. Vu        | <b>Art Unit</b><br>1618              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :3/13/08,7/30/07,7/10/07,6/22/07,12/19/06.

### **DETAILED ACTION**

Receipt is acknowledged of Applicant's Restriction Requirement Response filed on 07/09/09; Information Disclosure Statements filed on 03/13/08, 07/30/07, 07/10/07, 06/22/07, 12/19/06.

- Claims 1-9 are pending in the instant application.
- Claims 8-9 are withdrawn from consideration.

### ***Election/Restrictions***

Applicant's election of Group I (claims 1-7) and specie of PET/PAR in the reply filed on 07/09/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The 10th edition of the Merriam-Webster's Collegiate Dictionary (Merriam-Webster Incorporated: Springfield, Massachusetts, 1993, pp 311) defines "derivative" as, "a chemical substance related structurally to another substance and theoretically

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derivable from it.” For example, carbon could theoretically be derived from the combustion of prostaglandin. Therefore, the definition of derivative in the Merriam-Webster Collegiate Dictionary does not shed light on what Applicants’ intended for the meaning of a prostaglandin F2alpha derivative.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over MORISHIMA et al (WO 02/22131 published on 03/21/2002; wherein US 2004/0097592 is used as a translation) in view of.

Applicant's claims are directed to a product comprising of: a prostaglandin derivative, such as difluoroprostaglandin F2alpha derivative; a resin container, such as a polymer of polyethylene terephthalate and polyarylate; nonionic surfactant, such as polysorbate 80. Additional limitations include: liquid preparation; ratio of 1:4 to 4:1; eye drop; inhibiting the decrease of the prostaglandin derivative.

MORISHIMA teaches a product comprised of: a prostaglandin derivative, such as difluoroprostaglandin F2alpha derivative (see US 2004/0097592 at [0006]); a resin container, such as a polymer of polyethylene terephthalate or acrylic resin (see [0014]); nonionic surfactant, such as polysorbate 80 (see [0004]). Additional disclosures

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include: liquid preparation, such as ophthalmic solution (see [0001]), which reads on eye drop; inhibiting the active ingredient to be adsorbed to a resinous container (see abstract).

MORISHIMA does not specifically teach a resin container containing a copolymer of polyethylene terephthalate AND polyarylate with a ratio of 1:4 to 4:1.

KOIDE teaches using a resin container containing polyethylene terephthalate AND polyarylate (see translation at [0009]) for eye drop solutions containing nonionic surfactant (see [0006]). Additional disclosures include: the resin inhibits photolysis of the active ingredient (see [0001]) and inhibits the transference and adhesion of the active ingredient to the container (see [0002]); thus inhibiting the decrease of the active ingredient (see [0003]), which is the same objective as Applicant's claimed invention.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate a resin container containing a copolymer of polyethylene terephthalate AND polyarylate into MORISHIMA's product. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because both reference dealt with inhibiting the decrease of active agents in eye drop formulation using non-ionic surfactant and resin containers.

The references do not specifically teach adding the ingredients in the ratio amount as claimed by Applicant. The amount of a specific ingredient in a polymer is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be

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obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of ratio in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

***Telephonic Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jake M. Vu whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/  
Primary Examiner, Art Unit 1618